REMARKS

In the Office Action, claims 66-73 are rejected under 35 U.S.C. §102; and claims 66-73 are rejected under 35 U.S.C. §112, first paragraph. Claims 66 and 70 have been amended as previously provided. Applicants believe that the rejections should be withdrawn as further detailed below.

With respect to the §102 rejection, the Patent Office has rejected claims 66-73 as allegedly anticipated by Galin (U.S. Patent No. 4,443,441). The Patent Office essentially asserts that the Galin reference discloses each and every feature of the claimed invention.

Applicant believes that this rejection is improper. Of the pending claims at issue, claims 66 and 70 are the sole independent claims and are directed to an ophthalmic, night vision formulation that includes, in part, a therapeutically effective amount of a pharmaceutically active compound including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye so that a pupil size is effectively reduced to improve night vision. Claim 66 further recites that the formulation generates a redness response of about +1 or less on a scale of 0 to +4.

The formulations of the claimed invention can be used to optimize pupil size to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. This is an unexpected result since conventional ophthalmology would suggest that reducing pupil size in dim light would cause vision acuity to deteriorate.

In contrast, the primary focus of Galin relates to the use of alpha adrenergic blocking agents, particularly thymoxamine, to aid in the fixation of intraocular lenses. See, Galin, col. 1, lines 4-5. Indeed, Galin further discloses that this type of pupillary activity can reduce eccentric synechia formation and lens dislocation. See, Galin, column 1, line 61-67. Nowhere does Galin recognize that the reduction of pupil size in dim light can enhance night vision. Moreover, nowhere does Galin provide an ophthalmic formulation that combines pupil reduction in dim light with minimal eye redness properties as further defined in independent claim 66.

The claimed ophthalmic formulation utilizes a specific class of compounds known as alpha 1 antagonists to inhibit pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Ophthalmic

formulations that include such class of alpha 1 antagonist compounds can allow improvement in quality of vision in dim light (e.g., at night) without negative clinical effects in normal lighting conditions. See, Specification, page 13, paragraph 47. Moreover, Applicant has conducted experiments that demonstrate the beneficial effects of the claimed ophthalmic formulation. For example, Table 1 on page 27 of the specification demonstrates that ophthalmic formulations including an alpha 1 antagonist compound can reduce pupil diameter in darkness in increased amounts, and Table 2 on page 28 demonstrates the beneficial effects on night vision by reducing the pupil diameter in dim light. In Table 2, the glare and halo effects were reduced in addition to an improvement in depth perception by reducing the pupil diameter in dim light. See, Specification, page 28. Therefore, Applicants believe that Galin is distinguished from the claimed ophthalmic formulation.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, the Patent Office alleges that claims 66-73 are not enabling pursuant to §112, first paragraph. Applicant believes that the specification provides sufficient support such that one skilled in the art can practice the subject matter as presently claimed without undue experimentation.

Of the pending claims at issue, claims 66 and 70 are the sole independent claims as previously discussed. Contrary to the Patent Office position, Applicants believe that the specification provides sufficient guidance with respect to the alpha 1 antagonist active compound such that the claimed ophthalmic formulation can be practiced without undue experimentation. For example, on page 13, the specification provides that the claimed invention utilizes a specific class of compounds known as alpha 1 antagonists to inhibit pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Ophthalmic formulations that include such class of alpha 1 antagonist compounds can allow improvement in quality of vision in dim light without negative clinical effects in normal lighting conditions. See, Specification, page 13, paragraph 47. Indeed, a number of specific types of examples of alpha 1 antagonists include an imidazoline, such as phentolamine, and an alkylating agent, such as phenoxybenzamine, as further supported in the Specification, for example, on page 25 at paragraph 85.

Further, Applicant has conducted experiments that demonstrate the beneficial effects of the claimed invention. For example, Table 1 on page 27 of the specification demonstrates that four different types of alpha 1 antagonist compounds can reduce pupil diameter in darkness in increased amounts as compared to dapiprazole. Further, in Example 2, six additional specific types of alpha 1 antagonist compounds (e.g. tamsulosin, bunazosin, alfuzonsin, urapidil, ketanserin, and indoramin) are indicated to have some clinical effectiveness as well. See, Specification, page 25, paragraph 85. Moreover, Applicant conducted an additional test to demonstrate the beneficial effects on vision by reducing the pupil diameter in dim light as provided on page 28 of the specification.

Based on at least these reasons, Applicant believes that the specification provides sufficient support and guidance such that one skilled in the art can readily practice the claimed invention with undue experimentation. Therefore, Applicant believes that claims 66-73 satisfy the enablement requirement pursuant to 35 U.S.C. § 112, first paragraph.

Accordingly, Applicant respectfully requests that the examination of the present application be conducted in due course.

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

BY _____

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